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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,644	09/18/2001	Eric Silverberg	1893	1184

7590 01/26/2005

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,644	SILVERBERG ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and amendment, both filed 12/06/2004.

Claims 1-17 are pending.

Double Patenting

1. Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1-17 of U.S. Patent No. 6,077,527 ('527. Although the conflicting claims are not identical, they are not patentably distinct from each other because both of the instant application and the issued patent claim an adhesive composition comprising alkyl acrylate monomer and/or alkyl methacrylate monomer and nitrogen containing monomer. US '527 does not disclose reactive sites are present in the polymer after polymerization. The present claim language permits the presence of cross-linker claimed in US '527.

Response to Arguments

2. Applicant's arguments filed 12/06/2004 have been fully considered but they are not persuasive. Applicants traverse the double patenting rejection over US patent '527 by arguing that the conflicting claims directed to composition comprises crosslinker and compound comprising reactive hydrogen.

In response to this argument, the examiner position is that the claim language "lacks functional groups" does not exclude the functional group because the word "lack", according to the WEBESTER'S II Dictionary, means "to be without or have very little", and the US '527 claims as low as 0.2% of the compound comprising functional group and as low as 0.01% crosslinker and US '527 does not claim the presence of reactive sites after polymerization, i.e. no post-polymerization chemical crosslinker.

Claim Rejections - 35 USC § 102

3. Claims 1, 4, 5, 8-17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,730,999 ('999).

US '999 discloses a dermal therapeutic system which exhibits prolonged release of the drug comprising at least one pharmaceutical agent combined with adhesive composition. The adhesive composition comprising poly(meth)acrylates in the form of at least one layer of the therapeutic system. The poly(meth)acrylates are mixture of at least one (meth)acrylic polymer containing functional groups and selected from butyl-methacrylate and 2-ethyl hexyl methacrylate and at least one polymer which contains no functional group or only insignificant amount of functional groups, which is trimethylammonioethyl methacrylate that reads on non-cyclic nitrogen containing monomer (abstract; col.2, lines 66-67; col.3, lines 1-7; col.4, lines 30-37). The functional group containing polymers comprising 10-70%, and this means the polymer containing no functional group would form 90-30% of the composition (col.4, lines 1-17). The polymer composition has glass temperature from -10^0C to 100^0 C (col.3, lines 45-47).

The reference disclosed a dermal therapeutic system including a backing film and a release liner (col.5, lines 15-16, 26-30). The drugs to be delivered by the disclosed system include fentanyl (col.4, line 55). The reference does not disclose cross-linking agents or reactive groups in the composition.

Response to Arguments

4. Applicant's arguments filed 12/06/2004 have been fully considered but they are not persuasive. Applicants traverse the anticipatory rejection of claims 1, 4, 5, 8-17 over US '999 by arguing that the US '999 requires polymer containing functional group, while the present adhesive composition lacks functional groups containing reactive hydrogen moieties.

In response to the above argument, the examiner position is that US '999 disclosed adhesive composition comprising polymers without or with insignificant amounts of functional groups, and that what applicants are claiming. The expression "comprising " of the claim language permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive, even in major amounts. See *Moleculon Research Corporation v CBS, Inc.* 229 USPQ 805, *In re Baxter* 210 USPQ 795, 803. Therefore, the claim language permits the presence of polymers containing functional groups.

5. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,077,527 ('527).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '527 disclosed a pressure sensitive adhesive composition for use in transdermal drug delivery devices comprising at least 40% by weight of alkyl acrylate including n-butyl and 2-ethylhexyl acrylate, and 10-60% by weight of substituted acrylamide or methacrylamide including t-octyl acrylamide (abstract; col.2, lines 45-60; col.3, lines 60-67; col.4, lines 8-16). The Tg of the composition is calculated by the examiner to be below 10^0C. The reference does not disclose any reactive groups after the cross-linking.

Response to Arguments

6. Applicant's arguments filed 12/06/2004 have been fully considered but they are not persuasive. Applicants traverse the anticipatory rejection of claims 1-7 over US '527 by arguing that the composition disclosed by US '527 must contain crosslinker and must contain a compound comprising a reactive hydrogen.

In response to applicants' argument, the examiner position is that the claim language "lacks functional groups" does not exclude the functional group because the word "lack", according to the WEBESTER'S II Dictionary, means "to be without or have very little", and the US '527 disclosed as low as 0.2% of the compound comprising

functional group and as low as 0.01% crosslinker and US '527 does not disclose the presence of reactive sites after polymerization, i.e. no post-polymerization chemical crosslinker. The reference disclosed the crosslinker as an optional ingredient. The expression "comprising " of the claim language permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive, even in major amounts. See *Moleculon Research Corporation v CBS, Inc.* 229 USPQ 805, *In re Baxter* 210 USPQ 795, 803. Therefore, the claim language permits the presence of polymers containing functional groups.

Claim Rejections - 35 USC § 103

7. Claims 2, 3, 6 and 7 are rejected under 35 U.S.C. 103(a) as being obvious over US 5,730,999 ('999) in view of US '527.

The applied reference US '527 has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US '999 discloses a dermal therapeutic system which exhibits prolonged release of the drug comprising at least one pharmaceutical agent combined with adhesive composition. The adhesive composition comprising poly(meth)acrylates in the form of at least one layer of the therapeutic system. The poly(meth)acrylates are mixture of at least one (meth)acrylic polymer containing functional groups and selected from butyl-methacrylate and 2-ethyl hexyl methacrylate and at least one polymer which contains no functional group or only insignificant amount of functional groups, which is trimethylammonioethyl methacrylate that reads on non-cyclic nitrogen containing monomer (abstract; col.2, lines 66-67; col.3, lines 1-7; col.4, lines 30-37). The ratio of the functional and non functional polymers ranges between 20:1 to 1:20 depending on the release properties of the pharmaceutical agent and the flow behavior of the product blend (col.3, lines 9-14). The functional group containing polymers comprising 10-70%, and this means the polymer containing no functional group would form 90-30% of the composition (col.4, lines 1-17). The polymer composition has glass temperature from – 10^0C to 100^0 C (col.3, lines 45-47). The reference disclosed a dermal therapeutic system including a backing film and release liner (col.5, lines 15-16, 26-30). The drugs

to be delivered by the disclosed system include fentanyl (col.4, line 55). The reference does not disclose cross-linking agents.

However, US '999 does not teach the specific non-cyclic nitrogen containing monomer claimed in claims 2, 3, 6, and 7.

US '527 disclosed a pressure sensitive adhesive composition for use in transdermal drug delivery devices that possesses the ability to tolerate enhancers plasticization and to resist uncontrolled enhancer migration (col.2, lines 23-27). The adhesive composition comprising at least 40% by weight of alkyl acrylate including n-butyl and 2-ethylhexyl acrylate, and 10-60% by weight of substituted acrylamide or methacrylamide including t-octyl acrylamide (abstract; col.2, lines 45-60; col.3, lines 60-67; col.4, lines 8-16).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the adhesive composition disclosed by US '999 and replace the non-cyclic nitrogen containing monomer by the substituted acrylamide monomer disclosed by US '527, motivated by the teaching of US '527 that the composition having this combination possesses the ability to tolerate enhancers plasticization and to resist uncontrolled enhancer migration, with reasonable expectation of the delivered adhesive as a transdermal drug delivery carrier that effectively hold enhancer that are required for transdermal drug delivery.

Response to Arguments

8. Applicant's arguments filed 12/06/2004 have been fully considered but they are not persuasive. Applicants traverse the rejection of claims 2,3, 6 and 7 as being

unpatentable over US '999 in view of US '527 by arguing that combination of the references will result into composition comprising both functional and non-functional polymers and also crosslinker.

In response to applicants argument, the examiner position is that the expression "comprising " of the claim language permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive, even in major amounts. See *Moleculon Research Corporation v CBS, Inc.* 229 USPQ 805, *In re Baxter* 210 USPQ 795, 803. Therefore, the claim language permits the presence of polymers containing functional groups. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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